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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,133

07/23/2003

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,133

Applicant(s)

STAROBIN ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/15/03 & 12/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-37 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U. S. Patent No. 7,123,953.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '953 discloses the "risk of cardiac arrhythmia" which can be caused by cardiac ischemia. Therefore, it would be obvious to sense cardiac ischemia, a precursor to cardiac arrhythmias, to add in the determination of cardiac or cardiovascular health.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being obvious over Starobin et al. (US Patent Publication 20030130586 A1 (now U.S. 7,123,953), (hereafter referred to as Starobin et al '586). Starobin et al '586 discloses a method of assessing cardiovascular health, specifically the "predisposition to cardiac arrhythmias"(page 15, paragraph 191). Additionally, Starobin et al '586 discloses on page 15, paragraph 191, "all above-mentioned signal-processing steps may be used to quantitatively assess susceptibility to cardiac ischemia and, as a simultaneous option, cardiovascular system health of a particular individual under test".

Although, Starobin et al '586 discloses the claimed invention, as described below, except for the comparison of a first and second RR interval to each other. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the QT and RR interval comparison as taught by Starobin et al '586 with a just an RR interval comparison since Starobin et al '586 discloses that it was well known at the time the invention was made to compare the RR intervals to each other, as recited on page 3, paragraph 29, "the prior art methods are either concerned with their mean values, or spatial variations or, as in the case of the heart rate variability,

with temporal RR fluctuations considered without any reference to the QT fluctuations".
Therefore, it would have been obvious to just compare the RR interval.

As to claim 2, "part of the application software performs the next step (4e), which is smoothing, filtering or data fitting, using any suitable functions, in order to obtain sufficiently smooth QT and RR slow trends for each gradual stage"(page 15, paragraph 191).

As to claim 5, Starobin et al '586 discloses in claim 2, located in col. 34, that the "interval data sets are collected under quasi-stationary conditions".

As to claim 6-7, Starobin et al '586 discloses in claims 3 and 4, located in col. 34, that the "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are each at least 3 minutes in duration"(claim 3) and the "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are together carried out for a total time of from 6 minutes to 40 minutes"(claim 4).

As to claim 8, Starobin et al '586 discloses in claim 5, located in col. 35, that the "both said stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are carried out between a peak rate and a minimum rate; and said peak rates of both said stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are the same".

As to claims 10-11, Starobin et al '586 discloses in claims 6 and 7, located in col. 35, that the "stage of gradually decreasing heart rate is carried out at at least three different heart-rate stimulation levels"(claim 6) and the "stage of gradually increasing heart rate is carried out at at least three different heart-rate stimulation levels"(claim 7).

As to claim 12, Starobin et al '586 discloses in claim 8, located in col. 35, that the "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are carried out sequentially in time".

As to claim 13, Starobin et al '586 discloses in claim 9, located in col. 35, that the "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are carried out separately in time".

As to claim 14, Starobin et al '586 discloses in claim 10, located in col. 35, that the "said heart rate during said stage of gradually increasing heart rate does not exceed more than 120 beats per minute".

As to claim 15, Starobin et al '586 discloses in claim 11, located in col. 35, that the "said heart rate during said stage of gradually increasing heart rate exceeds 120 beats per minute".

As to claims 19-28, as depicted in figures 4a and 4b, the steps 47a and 47b, employs the steps of domain determination and the synthesis of a hysteresis loop.

As to claims 29-30, Starobin et al '586 discloses in claim 13, located in col. 35, "the steps of: (g) treating said subject with a cardiovascular therapy; and then (h) repeating steps (a) through (f) to assess the efficacy of said cardiovascular therapy, in which a decrease in the quantitative indicium from before said therapy to after said therapy indicates an improvement in cardiac health in said subject from said cardiovascular therapy".

As to claim 31, Starobin et al '586 discloses in claim 14, located in col. 35, "wherein said cardiovascular therapy is selected from the group consisting of aerobic

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exercise, muscle strength building, change in diet, nutritional supplement, weight loss, stress reduction, smoking cessation, pharmaceutical treatment, surgical treatment, and combinations thereof".

As to claims 32-37, Starobin et al '586 discloses the employment of a computer system and computer program to measure cardiac or cardiovascular health.

Claim Objections

1. Claims 6-7 are objected to because of the following informalities: "out at at least". The examiner recommends changing the claim to delete the repetition of "at".

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762


GEORGE R. EVANISKO
PRIMARY EXAMINER

5/14/7